

IN THE TITLE

Please amend the Title of the application, as follows.

--USE OF ODORANTS TO ALTER [VAGINAL] BLOOD FLOW TO THE VAGINA, AND
ARTICLE OF MANUFACTURE THEREFOR —

IN THE CLAIMS

Please amend the claims as shown in the attached replacement sheets submitted under 37 C.F.R. § 1.12(c). Claims 24-27, 32, 35, 41 and 45 have been amended. Claims 34, 37, 39, 40, 43, 47 and 48 have been canceled. A redline version is enclosed to illustrate the amendments to the claims.

IN THE SPECIFICATION

Please amend the specification as follows:

At page 12, line 15, delete "(n=19)" and insert therefore --(n=30)--.

REMARKS

Reconsideration of the pending claims based on the amendments and remarks presented herewith, is respectfully requested. Claims 1-33, 35, 36, 38, 41, 42, 44-46 are pending.

No new matter is added with the amendments.

Support for the amendment to Claim 24 is in Claim 34 (now cancelled). Claim 25 has been amended as an independent claim with the limitations of base Claim 24.

Support for the amendments to Claims 26-27 is in the specification at page 5, lines 4-7. Support for the amendment to Claim 32 (capped vessel) is in original Claim 29 (vessel having a cap) and the specification at page 7, lines 5 and 8-11.

Claim 35 has been amended as an independent claim with the limitations of base Claim 24. Support for the amendment to Claim 41 is in Claim 43 (now cancelled). Support for the amendment to Claim 45 is in Claim 47 (now cancelled).

The specification has been amended to correct the "n=" valve as n=30. Support for the amendment is at page 8, lines 21-22 ("thirty adult pre-menopausal, periallatory women....").

Rejections under 35 U.S.C. § 112(1).

The Examiner rejected Claims 24-48 under Section 112(1) for lack of enablement. This rejection is respectfully traversed.

The Examiner maintains that the specification is not enabling for an article of manufacture comprising any undefined odorant other than one of the particular listed commercial odorants or mixtures. The Examiner also maintains that the claimed odorants are highly subjective with respect to the actual odors being encompassed.

It is noted that the claims have been amended to particular odorant mixtures.

It is respectfully submitted that Applicant's disclosure is fully enabling for odorants manufactured by other sources than those provided. According to Section 112, an Applicant is required to teach how to use an invention, and it is well settled that it is not necessary that the specification disclose every operative example when one skilled in the art is fully apprised by the disclosure of what the invention is and how to use it. A disclosure that contains representative examples which provide reasonable assurance to one skilled in the art that the compounds falling within the scope of the claim will possess the described utility is all that is required.

The particular commercial sources are exemplary, and one skilled in the odorant arts would readily identify suitable odorants from other sources that have the recited odorant character and would achieve the desired effect to alter blood flow to the vagina when inhaled by a female individual, particularly in view of the commercial source odorants that are provided.

Furthermore, satisfaction of the enablement requirement of Section 112 is not precluded by the necessity for some experimentation, such as routine screening. The key word is "undue" not "experimentation." *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976). A considerable amount of experimentation is permissible if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Jackson*, 217 USPA 804 (Bd. App. 1982).

The character of the particular odorants recited in the claims is well-delineated, commercial source odorants are identified, and a working example is provided that would enable an art worker to obtain and employ such compounds as broadly as they are claimed.

Claims 25 and 35 have been amended to incorporate the limitations of the independent Claim 24. Claim 34 has been incorporated into base Claim 24. Claims 37 and 43 have been incorporated into Claim 41. Claim 38 depends from amended Claim 24. Claim 44 depends from amended Claim 41. It is therefore submitted that these claims as amended are in condition for allowance, and withdrawal of the rejection of these claims is requested.

As for the prior art rejections, the Examiner stated that the claims have been examined over the art "only insofar as they read on a cherry odorant."

In the rejections, the Examiner asserts that the term "decismel units" "...appears to be a unit of measure seldom used in the odorant art other than by applicant..." (see, for example, the Office action at page 7).

The Examiner is respectfully directed to the following patent and publication indicating the use of "decismels" as a concentration term:

U.S. Patent No. 6,324,475 (Hayes et al.) at col. 8, lines 56-64, col. 20, lines 62-65, (and elsewhere).

Amoore and O'Neill, *Proposal for a Unifying Scale to Express Olfactory Thresholds and Odor Levels: the "Decismel Scale,"* Olfacto-Labs, Berkeley, CA (1988), in Proceedings of the 1988 Air Pollution Control Association Annual Meeting, Paper No. 78.5 (21 pp.).

The term "decismel units" is an art-recognized term that is well understood by one of ordinary skill in the odorant arts.

Rejection under 35 U.S.C. §102(b)

The Examiner rejected Claims 24, 26-29, 31, 32, 36, 39, 41, 42 and 45-48 for lack of novelty under Section 102(b) based on USP 5,575,992 (Kunze), USP 4,285,468 (Hyman), or Sensorics, 1983 (Doty), with evidence provided by USP 4,493,869 (Sweeney). This rejection is respectfully traversed.

Kunze discloses a gel fragrance cartridge for dispensing a cherry or citrus perfume into the atmosphere that has an extended service life of 25-30 days. Hyman discloses an article for slow release of a volatilizable substance, including a cherry perfume. Doty discloses a smell identification test involving 50 microencapsulated odorants, including cherry, with Sweeney generally disclosing microcapsules that can contain fragrance materials.

The Examiner is also directed to Applicant's issued patents, for example:

USP 6,106, 837 with claims to a method and article of manufacture for treating headaches, reciting odorants (Claim 1: green apple, Claim 28: peppermint, banana) and providing a commercial source for the odorants in the specification at col. 3, lines 31-37.

USP 5,904,916 with claims to a method and article of manufacture for enhancing learning, recited odorants (Claim 1: floral odorant), and providing a commercial source for the odorants in the specification at col. 2, lines 6-9.

USP 5,885,614 with claims to a method and article of manufacture for increasing penile blood flow in a male individual, reciting odorants (Claims 1-3, etc.), and providing a commercial source for odorants in the specification at col. 2, lines 40-43.

USP 5,759,521 with claims to a method of altering perception of relative space of an area, reciting odorants (Claim 1: green apple, Claim 10: barbecue smoke) and providing a commercial source for the odorants in the specification at col. 2, lines 45-47.

It is respectfully submitted that the odorants recited in the claims are clear in their meaning, and the present disclosure of commercial sources of those odorants and a working example is more than adequate to enable one of ordinary skill in this art area to carry out the invention commensurate with the scope of claims, as required under Section 112(1).

Based on Applicant's disclosure and the understanding in the art, it is submitted that the requirements under Section 112(1) have clearly been met in the present disclosure, and that an art worker in this area is fully enabled to practice Applicant's invention as broadly as it is claimed.

Accordingly, it is respectfully submitted that the claims fully comply with Section 112(1), and withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. §112(2).

The Examiner rejected Claims 27, 34, 35, 37, 39, 40, 43, 44, 47 and 48 under Section 112(2) for the use of indefinite claim language.

The Examiner maintains that in Claim 27, it is unclear as to what a 25-55 decismel unit concentration refers to. As stated in the specification at page 5, lines 4-7 (emphasis added):

...it is preferred that *the subject individual is presented with the odorant* at a superthreshold concentration (e.g., about 25-55 decismel units), but not irritative level,...

Claims 26 and 27 have been amended to clarify that the unit dosage amount of the odorant is at the recited concentration.

Next, the Examiner considers that Claim 32 is indefinite as to what is being defined as a “tip” of the dispenser. Claim 32 has been amended to define the dispenser as a capped vessel having a tip impregnated with the odorant (as described in the specification at page 7, lines 5 and 8-11).

The Examiner also contends that the metes and bounds of the odorants recited in Claims 34, 35, 37, 39, 40, 43, 44, 47 and 48 are not clearly delineated. It is respectfully submitted that the nature of the recited odorants is not ambiguous to one skilled in the odorants arts and would be readily ascertainable.

The odorant characteristics of the odorants recited in the claims are well understood in the odorant arts, and one skilled in the odorant arts would readily identify suitable odorants from various sources that have the recited odorant character and would achieve the desired effect. Suitable odorants are those that are capable of altering blood flow to the vagina when inhaled by a female individual.

Further, the Examiner is directed to Applicant’s issued patents, as described above. Each of these issued patents claim various odorants (e.g., green apple, peppermint, banana, barbecue smoke) for methods of treatment and articles of manufacture, and disclose commercial sources for the odorants in the specification.

It is respectfully submitted, based on the present disclosure, that is well within the understanding in the art to identify appropriate odorants for use in Applicant’s invention. Accordingly, it is submitted that the claims as amended satisfy the requirements of Section 112(2), and withdrawal of this rejection is respectfully requested.

Acknowledgement of Allowable Subject Matter over Prior Art.

At page 6 of the Office Action, the Examiner acknowledged that the elected species – a mixture of cucumber and licorice-based odorants – is free of the art. Accordingly, it is submitted that any claims readable thereon are allowable.

It is further observed that no art rejections have been put forth for depending Claims 25, 34, 35, 37, 38, or 43-44.

The claims as amended recite odorant mixtures, and do not read on a cherry odorant. None of the cited references teach or suggest an article of manufacture comprising a container of the particular odorant mixtures recited in the pending claims.

Nor do the references teach or suggest a contained unit dosage amount of the recited odorant mixtures to alter blood flow to the vagina of a female individual. Kunze and Hyman merely describe articles for release of vaporizable/volatile substances to the surrounding atmosphere. Doty describes articles for release of odorants for inhalation to establish ratings of perceived intensity, pleasantness, familiarity, coolness-warmth, and irritation (pages 3-4, bridging paragraph; Fig. 1 at page 5), and to identify individual odorants (pages 6-7, and Fig. 2).

Clearly, there is nothing in any of the cited references that teaches or suggests Applicant's article of manufacture with the contained odorant mixtures, nor a unit dosage amount of the odorant mixtures to alter blood flow to the vagina of a female individual. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. §102(b) (Vlahakis)

The Examiner rejected Claims 24, 26-29, 31, 36, 39, 41, 42 and 45-48 under Section 102(b) as anticipated by USP 5,419,879 (Vlahakis). This rejection is respectfully traversed.

Vlahakis discloses a gel in a disposable container, comprised of a combination of chemical components including a cherry and other perfume component for use as a deodorizer.

The claims as amended recite odorant mixtures, and do not read on a cherry odorant. Vlahakis does not teach or suggest an article of manufacture comprising a container of the particular odorant mixtures claimed by Applicant.

Nor does Vlahakis teach or suggest a contained unit dosage amount of the recited odorant mixtures to alter blood flow to the vagina of a female individual. Rather, Vlahakis merely describes an article for release of vaporizable/volatilizable substances as a room deodorizer.

Accordingly, Vlahakis neither teaches nor suggests Applicant's invention as claimed, and withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. §102(e) and §103(a) (Nolicchia)

The Examiner rejected Claims 24, 26-31, 36, 39, 41, 42 and 45-48 under Sections 102(e) and 103 as anticipated by or obvious over USP 5,770,206 (Nolicchia). This rejection is respectfully traversed.

The basis of the Examiner's rejection is that the claimed invention is taught or obvious in view of Nolicchia's disclosure of a bottled body oil that comprises a cherry fragrance.

Nolicchia teaches body oils that can be *ingested*, and include fragrances and/or flavorants (e.g., cinnamon, peppermint, spearmint, cloves), and sensory materials that provide a hot or cold sensory stimulation. Nolicchia describes inclusion of a cherry *flavoring* – not fragrance – as a secondary flavorant. See at col. 1, lines 34-35 and 63-65 (“secondary flavorants such as cherry...”).

Nolicchia does not teach or suggest Applicant's article as claimed comprising a container of the recited odorant mixtures. Nor does Nolicchia teach or suggest a contained unit dosage amount of the recited odorant mixtures to alter blood flow to the vagina of a female individual. Rather, Nolicchia merely describes a body oil comprising sensory materials and flavorants/fragrances to provide pleasant aromas and a hot/cold sensory effect, which can be safely ingested.

Accordingly, withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. §103(a)

The Examiner rejected Claims 24, 26-33, 36, 39, 41, 42 and 45-48 under Section 103(a) as unpatentable over Kunze, Hyman, Doty, Vlahakis, and/or Nolicchia, in view of the admitted state of the art. This rejection is respectfully traversed.

The basis of the Examiner's rejection is that each of the references teaches the inclusion of a cherry fragrance in their products, and it would be obvious to utilize a “results-effective amount” – a non-irritating amount that is pleasant to the olfactory senses – of a commercially available odorant.

First of all, depending Claims 26-27 recite a *suprathreshold amount* but non-irritant amount of the odorant. As defined in the specification at page 5, lines 4-14, a “suprathreshold amount” is not a “pleasant amount.” Rather, a suprathreshold amount is a concentration beyond

that needed to be detected by a normosmic person but not at an irritant amount, i.e., a noxious or painful level. None of the cited references teaches or suggests a suprathreshold yet non-irritating amount of an odorant to achieve altering blood flow to the vagina of a female individual.

Further, the claims as amended recite odorant mixtures, and do not read on a cherry odorant. As discussed above, none of the cited references teach or suggest an article of manufacture as presently claimed comprising a container of the recited odorant mixtures.

Nor do the references teach or suggest a contained unit dosage amount of the recited odorant mixtures to alter blood flow to the vagina of a female individual.

As discussed above, Kunze and Hyman describe articles for release of volatile substances to the atmosphere. Doty describes articles for release of odorants for inhalation to test perceived intensity, pleasantness, familiarity, coolness-warmth and irritation, and to identify individual odorants. Vlahakis discloses a contained gel comprising a cherry or other perfume for use as a deodorizer. Nicolicchia describes ingestible body oils that fragrances/flavorants (e.g., cinnamon, peppermint, spearmint, cloves), hot/cold sensory materials, and a secondary *flavoring* such as cherry. None of the cited references address the alteration of blood flow to the vagina of a female individual.

Nothing in any of the cited references teaches or suggests Applicant's article of manufacture comprising the recited contained odorant mixtures, nor a unit dosage amount of the odorant mixtures to alter blood flow to the vagina of a female individual. Accordingly, withdrawal of this rejection is respectfully requested.

Extension of Time. Applicant hereby requests a two-month extension of time to extend the time for response to **February 24, 2002**. A check in the amount of \$55.00 is enclosed herewith to cover the extension fee. Please charge any additional fee required to Account No. 232053. Applicant is a small entity.

Supplemental Information Disclosure Statement. Applicant encloses herewith a Supplemental Information Disclosure Statement, Form 1449, and a copy of the listed references. Also enclosed is the required fee (\$180.00) for consideration of the listed references.

Based on the amendments and above remarks, it is submitted that the present claims are in condition for allowance, and notification to that effect is respectfully requested.

Respectfully submitted,



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Enclosures:

- Replacement Claim Sheets
- Redline version of claims showing amendments
- Cited patents, publications and cases
- Information Disclosure Statement, Form 1449, references

WHAT IS CLAIMED:

24. An article of manufacture, comprising, packaged together:

a unit dosage amount of an odorant packaged in a container, to alter blood flow to the vagina when inhaled by a female individual; wherein the odorant is selected from the group consisting a mixture of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber odorants, a mixture of lavender and pumpkin pie odorants, and a mixture of baby powder and chocolate odorants; and

instructions for administering the odorant to alter blood flow to the vagina.

25. ~~The~~An article of manufacture according to Claim 24, further comprising, packaged together:

a unit dosage amount of an odorant packaged in a container, to alter blood flow to the vagina when inhaled by a female individual;

instructions for administering the odorant to alter blood flow to the vagina; and
at least one of the following:

a device for measuring blood flow to the vagina of the female individual; and
means for testing olfactory ability in the female individual.

26. The article of manufacture of Claim 24, wherein the unit dosage amount comprises a concentration of the odorant is effective to provide a suprathreshold but not irritant amount of the odorant.

27. The article of manufacture of Claim 24, wherein the unit dosage amount comprises a concentration of the odorant is at about 25-55 decismel units.

28. The article of manufacture of Claim 24, wherein the odorant is packaged within a delivery device selected from the group consisting of a vial, jar, pouch, can, bottle, blister pack, and a scratch-and-sniff odor patch containing microcapsules of the odorant.

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29. The article of manufacture of Claim 24, wherein the odorant is in a form selected from the group consisting of a cloth scented with the odorant, an aerosol spray, a pump-type spray, a nasal spray, a liquid or solid form of the odorant contained in a vessel having a cap, a liquid or solid form of the odorant contained in a blister pack, and microcapsules of the odorant contained in a scratch-and-sniff odor patch.

30. The article of manufacture of Claim 24, wherein the odorant is in the form of a cream or a cologne.

31. The article of manufacture of Claim 24, wherein the odorant is in a liquid form contained in a dispenser.

32. The article of manufacture of Claim 31, wherein the dispenser has comprises a capped vessel having a tip impregnated with the odorant.

33. The article of manufacture of Claim 32, wherein the dispenser contains the odorant absorbed to a wicking material.

34. ~~The article of manufacture of Claim 24, wherein the odorant is selected from the group consisting a mixture of licorice based and banana nut bread odorants, a mixture of licorice based and cucumber odorants, a mixture of lavender and pumpkin pie odorants, and a mixture of baby powder and chocolate odorants.~~

35. The An article of manufacture of Claim 24, comprising, packaged together:
a unit dosage amount of an odorant packaged in a container, to alter blood flow to the
vagina when inhaled by a female individual; wherein the odorant comprises a mixture of a
licorice-based odorant and a cucumber odorant; and
instructions for administering the odorant to alter blood flow to the vagina.

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36. The article of manufacture of Claim 24, wherein the odorant and the unit dosage amount of the odorant is effective to increase blood flow to the vagina of the female individual by about 10-30%.

37. ~~The article of manufacture of Claim 36, wherein the odorant is selected from the group consisting of a mixture of a licorice-based and cucumber odorants, a mixture of a lavender and pumpkin pie odorants, and a mixture of a baby powder and chocolate odorants.~~

38. The article of manufacture of Claim 24, wherein the odorant and the unit dosage amount of the odorant is effective to decrease blood flow to the vagina of the female individual by about 10-20%.

39. ~~The article of manufacture of Claim 38, wherein the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, and a cherry odorant, and a mixture of licorice-based and cucumber odorants.~~

40. ~~The article of manufacture of Claim 38, wherein the odorant is selected from the group consisting of a licorice-based odorant, and a charcoal barbecue smoke odorant, and a cherry odorant.~~

41. An article of manufacture, comprising, packaged together:

a unit dosage amount of an odorant packaged in a container, to increase blood flow to the vagina when inhaled by a female individual; ~~wherein the odorant is selected from the group consisting of a mixture of a licorice-based and cucumber odorants, a mixture of a lavender and pumpkin pie odorants, and a mixture of a baby powder and chocolate odorants; and~~
instructions for administering the odorant to increase blood flow to the vagina.

42. The article of manufacture of Claim 41, wherein the odorant and the unit dosage amount of the odorant is effective to increase blood flow to the vagina of the female individual by about 10-30%.

43. ~~The article of manufacture of Claim 41, wherein the odorant is selected from the group consisting of a mixture of a licorice-based and cucumber odorants, a mixture of a lavender and pumpkin pie odorants, and a mixture of a baby powder and chocolate odorants.~~

44. The article of manufacture of Claim 41, wherein the odorant comprises a mixture of a licorice-based and cucumber odorants.

45. An article of manufacture, comprising, packaged together:

a unit dosage amount of an odorant packaged in a container, to decrease blood flow to the vagina when inhaled by a female individual; wherein the odorant is a mixture of licorice-based and cucumber odorants; and

instructions for administering the odorant to decrease blood flow to the vagina.

46. The article of manufacture of Claim 45, wherein the odorant and the unit dosage amount of the odorant is effective to decrease blood flow to the vagina of the female individual by about 10-20%.

47. ~~The article of manufacture of Claim 45, wherein the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, a cherry odorant, and a mixture of licorice-based and cucumber odorants.~~

48. ~~The article of manufacture of Claim 45, wherein the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, and a cherry odorant.~~

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